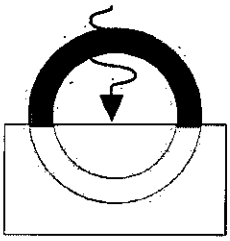
K120551

JUN - 8 2012



SIMUPLAN S.L.
Miguel Hernandez 25
La Eliana
46183 Valencia
Spain
Phone: (+34) 96-274-3827
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Date: February 8, 2012

Department of Health and Human Services
Center of Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification section

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k)

Company name:	**SIMUPLAN S. L.**
Registration #	pending
Address:	Miguel Hernandez 25
	La Eliana
	46183 Valencia
	Spain
Contact Person:	Conrado Pla Ph.D.
Phone:	(+34) 96-274-3827
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Device Name

Trade/Proprietary Name:	SIMUPLAN Treatment Planning System
Common/Usual Name:	Radiation Therapy Planning System
Classification Name:	Accelerator, Linear, Medical, Accessory 21 CFR 892.5050 Class II.

Legally Marketed Predicate devices(s)

Our device is substantially equivalent to the legally marketed predicate devices cited in the table below.

Manufacturer	Device	510(k) #
SIMUPLAN	SIMUPLAN Treatment Planning System, v 7.5	K030821
SIMUPLAN	SIMUPLAN Treatment Planning System, v 8.4	K093391

Description

The SIMUPLAN Treatment Planning System is computer based software that runs on a MacIntosh platform. The modified device, SIMUPLAN Treatment Planning System version 8.5, is a stereotatic radiosurgery module update only.

The planning process begins with the selection of the treatment machine (linear accelerator) and the image set that will be used for treatment planning. The patients' image sets (i.e. CT, MR, etc.) are imported into the system by standard methods: DICOM, disk, etc. From this data the stereotatic frame is localized and the patients' anatomical structures and tumor site are contoured. The treatment plan will be calculated from the target volume, isocenter, treatment machine and prescription dose and a dose distribution will be displayed. This treatment plan can be modified by the physician prior to final output and patient treatment. The physician approved treatment plan is then printed out and a hard copy of the isodose distribution is prepared for the patients' permanent record. The patient data is then saved under a unique file name in the patient database. The program output does not directly treat the patient; all information must be confirmed by the physician prior to treatment.

Intended use

SIMUPLAN Treatment Planning System is intended for use in preparing individual treatment plans for patients undergoing radiation therapy treatment with external beam or brachytherapy. The program output does not directly treat the patient; all information must be confirmed by the physician prior to treatment.

Summary of technological considerations

The SIMUPLAN Treatment Planning System software is substantially equivalent to the predicate devices.

Conrado Pla

Name: Conrado Pla Ph.D.
Title: President
SIMUPLAN S. L.

Mar 12, 2012

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SIMUPLAN S.L.
% Ms. Lu Anne Johnson
US Agent – SIMUPLAN S.L.
Capamed Inc.
1917 29 ¾ Avenue
RICE LAKE WI 54868

JUN - 8 2012

Re: K120551
Trade/Device Name: SIMUPLAN Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: April 9, 2012
Received: May 15, 2012

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: SIMUPLAN Treatment Planning System

Indications for Use:

SIMUPLAN Treatment Planning System is intended for use in preparing individual treatment plans for patients undergoing radiation therapy treatment with external beam or brachytherapy. The program output does not directly treat the patient; all information must be confirmed by the physician prior to treatment.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 120551